Effects of Water-Circulating Cooling Mask on Postoperative Outcomes in Orthognathic Surgery and Facial Trauma

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Abstract: The purpose of this study was to perform a systematic review and meta-analysis of randomized clinical trials (RCTs) investigating the efficacy of hilotherapy on postoperative pain, swelling, neurosensory impairment and patient satisfaction. The authors analyzed RCTs comparing the use of hilotherapy versus conventional cryotherapy or no cold treatment for orthognathic surgery and repair of facial trauma. The authors assessed the risk of bias and strength of evidence according to the Cochrane guidelines and GRADE rating system, respectively. Treatment effects were defined as weighted or standardized mean difference using the inverse variance method. Five RCTs were included. Postoperative pain and swelling in patients using hilotherapy were lower comparing to the control group in the postoperative day 2 (Pain: MD −1.75, CI 95% −2.69 to −0.81; Swelling: MD −21.16 mL, CI 95% −38.91 to −3.41) and in the final evaluation (Pain: MD −0.31, CI 95% −0.44 to −0.18; MD −4.45 mL, CI 95% −7.87 to −1.03). Patients reported higher satisfaction with hilotherapy, but no differences were found for neurosensory impairment. Current evidence suggests that hilotherapy is effective in reducing postoperative pain and swelling in orthognathic surgery and repair of facial fractures and may lead to improvements in patient satisfaction in the recovery phase.

Key Words: Cryotherapy, mandibular fractures, orthognathic surgery, postoperative pain

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Postoperative pain and facial swelling are common occurrences after orthognathic surgery and repair of facial fractures and are thought to arise from inflammatory response which is a direct and immediate consequence of the surgical procedure and trauma. These complications may limit patients' daily functions and compromise their quality of life. Furthermore, it has been shown that patients submitted to orthognathic surgery reported that pain and swelling experienced immediately postoperatively were worse than expected which may lead in dissatisfaction with the treatment.[1,2] Several methods[3–8] have been evaluated for controlling postoperative morbidities after major oral and maxillofacial surgeries but in clinical practice commonly include cooling therapy and administration of anti-inflammatory and analgesic drugs.

In addition, cryotherapy has been used as a non-pharmacological intervention in the short-term recovery and is defined as the application of substances that remove heat from the body leading to vasoconstriction of blood vessels and decrease of tissue metabolism, microvascular permeability and nerve conduction velocity. Cryotherapy includes numerous techniques to induce heat abstraction such as ice pack, ice compresses, frozen gel packs, and ice chips in a plastic bag or in a washcloth[9] Recently, evidence has emerged on the application of cold compression at a regulated temperature through a face mask cold compression therapy, known as hilotherapy.[10–14]

Hilotherapy uses a preshaped thermoplastic polyurethane mask to channel a current of cool, demineralized water adjacent to the skin to provide regulated cryotherapy.[15] The polyurethane mask adapts easily to the patients' morphology, restricts the hypothermic effect to the areas affected by injury, and avoids abrupt temperature gradients.[16] It is adjusted to the desired temperature, from +10 to +35°C, and has been shown promising results in clinical trials with patients submitted to orthognathic surgery[15,17] and facial bone fracture treatment.[13,18] The aim of this systematic review and meta-analysis was to summarize results from individual studies on the effects of hilotherapy on postoperative pain, facial swelling, neurosensory impairments and patient satisfaction after orthognathic surgery and repair of facial trauma.

MATERIAL AND METHODS

This study was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[19] and supplemented by guidance from the Cochrane Collaboration Handbook.[20] Institutional review board approval and informed consent were not required for this systematic review and meta-analysis.

Search Strategy

Searches for randomized clinical trials (RCTs) were performed in PubMed, Web of Science, SCOPUS, Cochrane Central Register of Controlled Trials (CENTRAL), and the website clinicaltrials.gov (international database for clinical trials) from inception to

September 2019. A grey-literature search included Google Scholar and OpenThesis. The search was restricted to studies published in full-text versions, without language restriction. The reference lists of all eligible studies and reviews were also scanned to identify additional studies for inclusion. The structured search strategy used the following terms: (hilotherapy OR hilotherm) AND (orthognathic OR jaw surgery OR osteotomy OR mandibular OR maxillary OR bimaxillary OR craniomaxillofacial OR maxillomandibular OR sagittal split OR zygomatic OR trauma OR fractures). To expand the number of eligible articles, there was no use of filters in the search.

Study Selection and Eligibility Criteria

Two reviewers (TSS and PRO) independently screened the search results and identified studies that were potentially relevant based on their title and abstract. Relevant studies were read in full-text and selected according to eligibility criteria. Disagreements between the 2 reviewers were resolved by consensus or by a third reviewer (PRSM-F).

The following elements were used to define eligibility criteria:

(1) population: patients submitted to orthognathic surgery or treatment of facial fractures;
(2) intervention and controls: hilotherapy versus conventional cryotherapy or no treatment control group;
(3) outcomes: primary outcome was postoperative pain and secondary outcomes were postoperative facial swelling, neurosensory impairment and patient satisfaction;
(4) study type: RCTs.

Eligible studies must report at least one of the outcomes of interest. Publications were excluded if outcome data could not be summarized.

Data Extraction and Risk of Bias Assessment

Using a standardized data extraction sheet, the following information from the studies were extracted: demographic characteristics of study participants, surgical procedure, medication protocol, details of cryotherapy, and outcome data.

Risk of bias was assessed according to the Cochrane guidelines for RCTs. Seven domains were assessed for evaluation: sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other potential sources of bias. Risk of bias was rated as low, unclear, or high according to established criteria.[21]

Data Synthesis

Treatment effects were defined as weighted mean difference (WMD) or the standardized mean difference (SMD) using the inverse variance method and random-effects model. Weighted mean difference was calculated when the outcome measure in all RCTs was determined using the same scale, and SMD when outcomes were measured using different scales. To calculate the effect sizes, means and standard deviations (SD) were obtained for each study group and outcome of interest. If the means and standard deviations were not directly reported in the publication, the methods for estimation proposed by Hozo et al were used.[22] A negative effect size indicated that hilotherapy was effective in reducing postoperative pain, facial swelling and neurosensory impairment, and improving patient satisfaction with treatment.

A forest plot was used to graphically present the effect sizes and the 95% confidence interval (CI). A 2-tailed $P < 0.05$ was used to determine significance. Statistical heterogeneity was assessed using the Cochran Q test[23] and quantified by the I^2 index.[24] A subgroup analysis was performed according to the follow-up time. Although funnel plots may be useful tools in investigating small study effects in meta-analyses, they have limited power to detect such effects when there are few studies.[25] Therefore, because we had a small number of included studies, we did not perform funnel plot analysis. Analyses were conducted using the Review Manager 5.3 (Cochrane IMS, Copenhagen, Denmark).

Grading the Strength of Evidence

We graded the strength of evidence for the effect of hilotherapy on primary outcome as high, moderate, low or very low using the GRADE rating system. In the GRADE system, RCTs begin as high-quality evidence, but may be rated down by one or more of 5 categories of limitations: risk of bias, inconsistency (heterogeneity), indirectness of evidence, imprecision and publication bias.[26,27]

RESULTS

Data Sources

Search strategy yielded 80 potentially relevant studies. After screening titles and abstracts, 9 full-text articles were assessed for eligibility and 4 studies were excluded: 1 study compared the effectiveness of ice bags and ice towel in reducing postoperative discomfort after orthognathic surgery[28]; 1 study used only hilotherapy at a cooling temperature of 18°C or 22°C;[10] and in 2 studies outcome data could not be extracted[16,29] Finally, 5 RCTs[12,13,17,18,30] were included in the meta-analysis. A flow diagram of the study selection process is detailed in Supplementary Digital Content, Figure 1, http://links.lww.com/SCS/B466.

Study Characteristics and Surgical Protocols

The total number of patients included in this systematic review was 194 and most of them were young male. Two studies included only patients submitted to orthognathic surgery,[17,30] 2 studies evaluated patients with facial fractures,[13,18] and 1 study included patients submitted to orthognathic surgery or subjected to facial trauma with middle third and/or mandibular fractures.[12] For patients submitted to orthognathic surgery, the surgical procedures were Le Fort I osteotomy of the maxilla and sagittal split osteotomy of the mandible. Drug therapy included systemic antibiotics, analgesics, and steroids (single perioperative dose of intravenous prednisolone or postoperative dexamethasone for 3 days). Details of study characteristics and surgical protocols are described in Supplementary Digital Content, Table 1, http://links.lww.com/SCS/B465.

Cryotherapy Protocols

Patients randomized in the intervention group were treated with a water-circulating cooling system that consisted of a thermoplastic polyurethane mask connected to the Hilotherm device (Hilotherm GmbH, Germany). Patients used the cooling mask for at least 12 hours daily, maintained at a temperature of 15°C, during 72 hours after surgery.

In three studies,[13,17,18] patients randomized in the control group were treated with conventional cryotherapy (cool compresses or cold packs) during 72 hours. In 2 studies,[12,30] patients did not receive cryotherapy.

Outcomes Assessment

All studies included in this systematic review evaluated postoperative pain using a traditional 10-cm visual analogue scale (VAS). Four studies analyzed facial swelling: 3 studies[13,17,18] used

3D optical scanning technology and measured the amount of swelling by volume (mL), and 1 study[12] used linear distances in centimeters between tragus and external canthus, lateral ala of the nose, lip commissure, most prominent point of the chin skin, and angle of the mandible.

In 3 studies,[13,17,18] neurological analysis was used to evaluated nerve dysfunctions after surgery and consisted of cotton test for touch sensation, a pinprick test using a needle for sharp pain, and a blunt instrument for testing pressure. The results were graded with a score ranging from 0 to 9[13] or 13,[17,18] with the highest value being the worst neurological score. In these studies, patients were asked to complete a questionnaire rating their comfort and satisfaction with the applied postoperative cooling therapy. The grading scale ranged from 1 to 4, where 1 denoted "very satisfied" and 4 "not satisfied."

Risk of Bias

All RCTs had unclear information on random sequence generation and allocation concealment, and a high risk of performance bias since patients were informed that the study was designed to compare the effect of hilotherapy and conventional cryotherapy after surgery. However, most studies had a low risk of detection and attrition bias. One study had a low risk of selective reporting of prespecified outcomes (Supplementary Digital Content, Figure 2, http://links.lww.com/SCS/B466).

Data Synthesis and Subgroup Analysis

Primary Outcome

Postoperative Pain

The 5 RCTs included in this meta-analysis provided sufficient data for pain evaluation during the first postoperative week. Pain in patients using hilotherapy was lower when compared to the control group. Differences in pain intensity were found on postoperative day 2 (MD −1.75, CI 95% −2.69 to −0.81, $P = 0.0003$) and in the final evaluation (MD −0.31, CI 95% −0.44 to −0.18, $P < 0.0001$) (Fig. 1).

Secondary Outcomes

Facial Swelling and Neurosensory Evaluation

Three RCTs using 3D optical scanning technology provided sufficient data to analyze the effects of hilotherapy on facial swelling. The amount of swelling in patients receiving hilotherapy was significantly lower when compared to the control group. Differences were found on postoperative day 2 (MD −21.16 mL, CI 95% −38.91 to −3.41, $P = 0.02$), day 3 (MD −24.81 mL, CI 95% −47.11 to −2.51, $P = 0.03$) and in the final evaluation (MD −4.45 mL, CI 95% −7.87 to −1.03, $P = 0.01$) (Fig. 2). No differences were found between groups regarding improvement in neurosensory impairment (SMD −0.16 mL, CI 95% −0.52 to 0.21, $P = 0.40$) (Fig. 3).

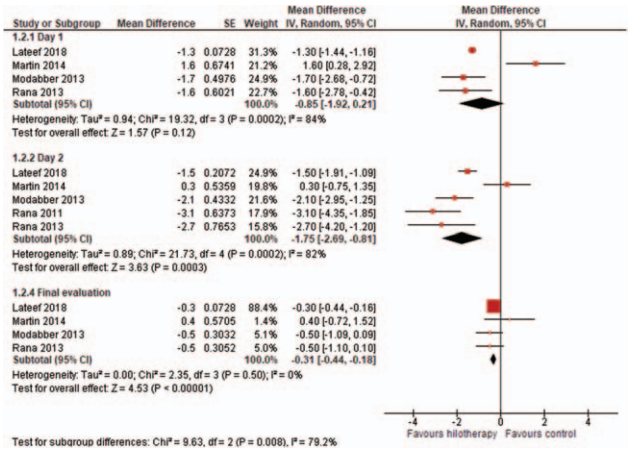

FIGURE 1. Forest plot of postoperative pain for patients using hilotherapy comparing with controls.

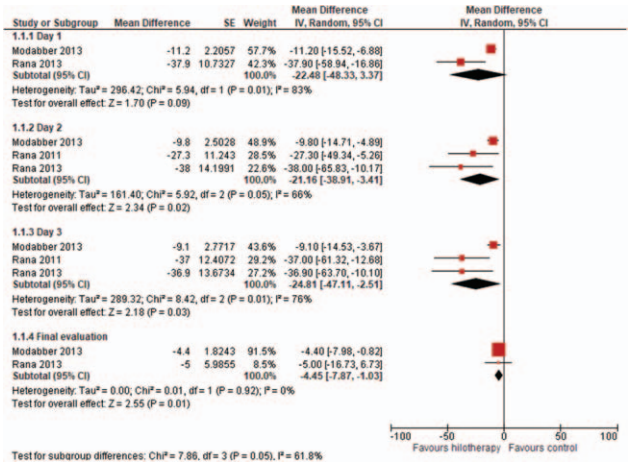

FIGURE 2. Forest plot showing the effects of hilotherapy on facial swelling.

Patient Satisfaction

Three RCTs evaluated the comfort and satisfaction with the applied postoperative cooling therapy. Patients using hilotherapy were more satisfied with the cooling treatment compared with those using conventional therapy (MD −0.96, CI 95% −1.28 to −0.64, $P < 0.0001$) (Fig. 4).

Strength of Evidence

We graded the effect of halotherapy on postoperative pain in patients submitted to major oral and maxillofacial surgery as moderate quality of evidence as per the GRADE criteria (Supplementary Digital Content, Table 2, http://links.lww.com/SCS/B465).

DISCUSSION

Postoperative morbidity is a major complication following orthognathic surgery and surgical management of facial fractures. This meta-analysis evaluated the efficacy of hilotherapy in reducing postoperative complications after major oral and maxillofacial surgery and showed a decrease of pain intensity and facial swelling for patients receiving the cooling mask compared to the control group during the first week after surgery. In addition, patients

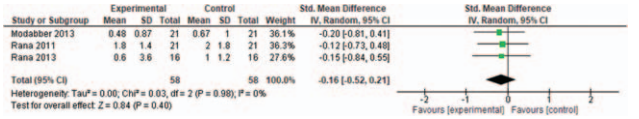

FIGURE 3. Forest plot showing the effects of hilotherapy on neurosensory impairment.

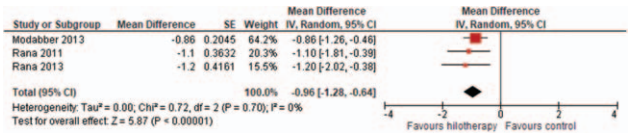

FIGURE 4. Forest plot showing the effects of hilotherapy on patient satisfaction comparing with controls.

reported higher satisfaction with cooling device, but comparable results were found after hilotherapy or intermittent cold therapy concerning neurosensory impairments.

The inflammatory response related to surgery and to trauma is defined as a surgical inflammation[31] and has been described as a succession of 3 functional phases that include an initial electrical phase with upregulation of ionic channel expression in nociceptive circuits leading in spontaneous neural firing; an intermediate immune phase with release of several endogenous substances including histamine, bradykinin and prostanoids; and a final endocrine phase with neurotrophic factors associates with structural neural remodeling.[31–34] The noxious stimuli arise from surgical procedures and trauma due to the osteotomies / fractures of facial bones, periosteal and muscle stripping can lead to moderate and severe postoperative pain and swelling. Therefore, adequate management of postoperative complications is essential for enhanced recovery and early return to function.[35]

Although the use of steroids and non-steroidal anti-inflammatory agents, the knowledge of possible beneficial effects of cold-induced vasoconstriction on reducing postoperative complications has allowed the empirical use of such therapy in oral and maxillofacial surgery. The decrease of skin temperature during cryotherapy leads to increase in pain threshold and tolerance due to the thermal effects on nerve fibers membranes, and reduction of inflammatory process due to decreasing cellular metabolism and temporary vasoconstriction. Studies have reported that a therapeutic skin surface temperature is accepted ranging from 10°C to 15°C, which allows comfort of the patient during cryotherapy and increases patient compliance with the treatment.[9,36,37] During hilotherapy, a water-circulating cooling device is applied directly to the face after surgery maintaining a desire temperature of 15°C over a continuous period of time with positive physiological effects in the recovery phase.

Although cryotherapy is largely used in oral and maxillofacial surgery, the scientific evidence of the efficacy of such therapy is sparse. In a recent meta-analysis,[38] we showed a decrease of pain intensity for patients receiving cold packs during the second and third days after third molar surgery, but the magnitude of the effect was small to moderate. Furthermore, the results of the meta-analysis showed no additional benefits in reducing trismus and facial swelling during the first postoperative week, which may be related to the sporadic and discontinuous decreasing temperature of conventional cooling. Unfortunately, there is no clear evidence regarding the most effective method of cold application and length of treatment, and the results from head-to-head trials comparing cooling techniques after oral surgery are limited. In the present meta-analysis, most studies compared the facemask with conventional cryotherapy and the results suggested improvements in postoperative outcomes in the short-term. The finding that hilotherapy was more effective than conventional cooling may be the result of differences in surface contact since the cooling mask is applied across a wider anatomic area,[39] is not subject to interruptions and is not affected by the state of consciousness or cooperation of the patient.[16]

Functional and aesthetic improvements after major oral and maxillofacial surgery must be incorporated simultaneously to ensure patient satisfaction and psychological stability.[40,41] It has been shown that hilotherapy may lead in a reduction of anxiety levels and improvements in quality of life during the first postoperative week in third molar surgeries, and a faster return to normal daily activities.[11] In the present meta-analysis, we showed that patients treated with cooling mask had a higher overall satisfaction than patients using conventional cooling. Despite the continuous use of an external cooling device during the first 72 hours after surgery, the higher patient satisfaction treated with hilotherapy may be related to the reduction of postoperative pain and facial swelling. There is evidence that impulses from third-order neurons project to different areas in the sensory cerebral cortex and to the limbic system and contribute to the sensory-discriminative and affective-emotional component of pain.[42]

Studies have found other potential benefits of continuous cold flow device after surgical procedures. Patients receiving hilotherapy cooling had a significant reduced postoperative hospital stay after orthognathic surgery compared with those undergoing conventional cooling which may results in a decrease risk of nosocomial infection and in-hospital morbidity and mortality.[17] In addition, hilotherapy seems to improve the postoperative mouth opening after orthognathic surgery.[17] In anterior cruciate ligament reconstruction, hilotherapy resulted in lower pain perception, blood loss, knee volume increase, and higher range of motion in the first postoperative day.[43] However, no positive results were found after total knee arthrosplasty[44] and facelift procedure.[45] In the present meta-analysis, no differences were found concerning the neurological analysis in the short-term. In orthognathic surgery, the frequency of neurosensory impairments is higher than 60% during the first postoperative week[46] and their treatment remains a complex problem and are not always easily resolved.[47] Based on the results of this study, there is no evidence for recommendation of hilotherapy in the treatment of neurosensory disorders after orthognathic surgery and surgical repair of facial fractures.

The study has also some limitations. Despite the randomization of the patients, neither the patient nor the assessor could be blinded due to the nature of the intervention. Furthermore, although the potential physiological effects of hilotherapy, the high costs of the cooling device with Hilotherm may be expensive for some patients[12] and should be limited to selected cases, when more practicality and more compliance to the cryotherapy may equal the cost of the device.[44]

CONCLUSIONS

The current available evidence suggests that hilotherapy is effective in reducing postoperative pain and facial swelling in orthognathic surgery and surgical management of facial fractures and may lead to improvements in patient satisfaction and comfort in the recovery phase. Hilotherapy must be considered as an effective option in the management of pain and swelling in advanced postoperative recovery protocols for oral and maxillofacial surgeries.

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